REMARKS

Applicants would like to thank Examiners Karen E. Toth and Robert Nasser for the very courteous and helpful discussion held with their representative on April 27, 2007. The substance of this interview is summarized in the remarks below.

As discussed during the interview, the term "about" has been deleted from the numerical contact area limits recited in independent claims 1, 19, and 24 for purposes of clarification and in accordance with Examiner Nasser's suggestion.

As explained during the interview, the contact areas recited in rejected independent claims 1, 19, and 24 provide surprising and unexpected results. For example, as described in the specification, when the contact area of the electrode part and the extraction region of the skin exceeds about 50 mm^2, as in conventional devices, the current becomes concentrated in part of the analyte transmission path (i.e., paths formed by the application of electrical energy to the skin, which enlarges macropores such as sweat glands, pores or the like, and intercellular micropores); as a result, a long time is required until a predetermined number of analyte transmission paths are formed, and the waiting time is increased before analyte can be extracted (specification, page 27, lines 27-33).

By contrast, the claimed extraction devices and extraction methods involve a smaller electrode extraction region and contact area than do conventional extraction devices and methods. Surprisingly and unexpectedly, these smaller areas make it more difficult for the current to become concentrated in only some of the analyte transmission paths. Therefore, the number of analyte transmission paths becomes stable in a short time after starting the current flow, and the amount of extracted analyte becomes stable in a shorter time; that is, the waiting time before extraction of the analyte is reduced (specification, page 9, lines 13-23).

As further discussed during the interview, none of the applied references, individually or in combination, teaches or suggests the claimed contact areas with "sufficient specificity" as to constitute an anticipation of the claims. Moreover, in view of the surprising and unexpected results provided by the claimed contact areas, none of

the applied references, individually or in combination, would have rendered the claimed invention obvious.

Claim Rejections – 35 U.S.C. § 102

1. The rejection of claims 1, 4-7, 13, 15, 17-18, 24-25, 28-29, and 36 under 35 U.S.C. § 102(b) as being anticipated by *Conn et al.* (U.S. Patent No. 6,438,414) is respectfully traversed. At a minimum, *Conn et al.* does not teach or suggest with sufficient specificity "a contact area with the skin of between 0.01 and 50 mm^2," as required by each of independent claims 1 and 24. Moreover, *Conn et al.* does not teach or suggest "placing a first extraction electrode part on the skin in which the analyte transmission paths are already formed," as required by independent claim 29.

Conn et al. describes transdermal sampling systems using electrodes "configured to provide an approximate electrode area of 0.3 to 1.0 cm^2" (col. 18, lines 1-6)—a broad range that corresponds to an electrode area of 30 mm^2 to 100 mm^2. Moreover, *Conn et al.* identifies a preferred area of 0.85 cm^2 (85 mm^2), which lies well above the upper limit recited in independent claims 1 and 24. Applicants respectfully submit that the description in *Conn et al.* does not disclose the claimed contact areas with sufficient specificity for at least the reasons set forth below.

As noted in MPEP 2131.03(II) [emphases added]:

> When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, **the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute."** What constitutes a "sufficient specificity" is fact dependent. **If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.** The unexpected results may also render the claims unobvious.

Applicants respectfully submit that the broad range described in *Conn et al.* lacks "sufficient specificity" to constitute an anticipation of independent claims 1 and 24 under the statute—particularly since the specific preferred area of 85 mm^2 lies well outside the claimed range. Moreover, in view of the surprising and unexpected results achieved by the claimed contact areas, Applicants respectfully submit that the claimed invention would not have been obvious in view of *Conn et al.*

Recent legal precedent from the U.S. Court of Appeals for the Federal Circuit (CAFC) reaffirms that a prior art disclosure of a claimed range must be with sufficient specificity in order to constitute an anticipation of a claim. *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006). The CAFC further rules that the disclosure of a range in a reference does not constitute disclosure of the endpoints of a claimed range nor of the intermediate points. *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d at 1000.

Thus, inasmuch as *Conn et al.* does not teach or suggest the contact areas recited in independent claims 1 and 24 with sufficient specificity, and in view of both the surprising and unexpected results achieved by the claimed contact areas as well as the legal precedent establishing that the disclosure of a range does not constitute disclosure of the endpoints of a claimed range, Applicants respectfully submit that independent claims 1 and 24, and the claims dependent thereon, are neither anticipated by nor would have been obvious in view of *Conn et al.*

With regard to the rejection of claims 29 and 36, independent claim 29 recites "placing a first extraction electrode part on the skin in which the analyte transmission paths are already formed." In other words, the first extraction electrode part is placed on the skin after analyte transmission paths have already been formed. However, *Conn et al.* does not teach or suggest placing an extraction electrode part on skin in which analyte transmission paths have previously been formed, as required by independent claim 29. Thus, Applicants respectfully submit that independent claim 29, and claim 36 dependent thereon, are neither anticipated by nor would have been obvious in view of *Conn et al.*

For at least the reasons set forth above, withdrawal of the above grounds of rejection is respectfully requested.

2. The rejection of claims 19-20 and 22 under 35 U.S.C. § 102(e) as being anticipated by *Kim et al.* (U.S. Patent No. 6,736,777) is respectfully traversed. At a minimum, *Kim et al.* does not teach or suggest with sufficient specificity "a contact area with the skin of less than 50 mm^2," as required by independent claim 19.

Kim et al. describes biosensor systems using platinum electrodes "configured to provide a geometric surface area of about 0.1 to 3 cm^2" (col. 12, lines 6-28)—a broad range that corresponds to an electrode area of 10 mm^2 to 300 mm^2. Moreover, *Kim et al.* identifies a most preferred area of 1 cm^2 (100 mm^2), which lies well above the upper limit recited in independent claim 19. Applicants respectfully submit that the description in *Kim et al.* does not disclose the claimed contact areas with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Inasmuch as *Kim et al.* does not teach or suggest the contact areas recited in independent claim 19 with sufficient specificity, and in view of both the surprising and unexpected results achieved by the claimed contact areas as well as the legal precedent establishing that the disclosure of a range does not constitute disclosure of the endpoints of a claimed range, Applicants respectfully submit that independent claim 19 and claims 20 and 22 dependent thereon are neither anticipated by nor would have been obvious in view of *Kim et al.* Accordingly, withdrawal of this ground of rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

1. The rejection of claims 3, 8-11, 26-27, and 32 under 35 U.S.C. § 103(a) as being unpatentable over *Conn et al.* in view of *Avrahami et al.* (U.S. Patent Publication No. 2004/0230227) is respectfully traversed. At a minimum, *Conn et al.* and *Avrahami et al.* do not teach or suggest with sufficient specificity the range of contact area recited in independent claims 1 and 24. Moreover, *Conn et al.* and *Avrahami et al.* do not teach or suggest "placing a first extraction electrode part on the skin in which the analyte transmission paths are already formed," as required by independent claim 29.

As presently written, independent claim 1, from which rejected claims 3 and 8-11 depend, and independent claim 24, from which rejected claims 26 and 27 depend, recite a

range of contact areas between 0.01 and 50 mm^2. *Conn et al.* does not disclose the contact areas recited in independent claims 1 and 24 with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Avrahami et al. describes an apparatus and method for transdermal drug delivery and analyte extraction in which the contact area of electrodes on the skin is a circle having a diameter between 10 and 100 microns (page 13, paragraph 188)—a range that corresponds to an electrode area of 7.85×10^{-5} to 7.85×10^{-3} mm^2. This range is below the lower limit of 0.01 mm^2 presently recited in independent claims 1 and 24. As explained in the specification, "when the contact area of the electrode part and extraction region of the skin is less than about 0.01 mm^2, a long time is required to extract the amount of analyte necessary for analysis" (page 28, lines 1-4).

Thus, inasmuch as neither of *Conn et al.* nor *Avrahami et al.* teaches or suggests the contact areas recited in independent claims 1 and 24 with sufficient specificity, and in view of the surprising and unexpected results achieved by the claimed contact area, Applicants respectfully submit that independent claims 1 and 24, and the claims dependent thereon, are neither anticipated by nor would have been obvious in view of these references, individually or in combination.

With regard to the rejection of claims 29 and 32, independent claim 29, from which claim 32 depends, recites "placing a first extraction electrode part on the skin in which the analyte transmission paths are already formed." In other words, the first extraction electrode part is placed on the skin after analyte transmission paths have already been formed. Neither *Conn et al.* nor *Avrahami et al.* teaches or suggest placing an extraction electrode part on skin in which analyte transmission paths have previously been formed, as required by independent claim 29. Thus, Applicants respectfully submit that independent claim 29 and claim 32 dependent thereon, are neither anticipated by nor would have been obvious in view of these references, individually or in combination.

For at least the reasons set forth above, withdrawal of the above grounds of rejection is respectfully requested.

2. The rejection of claim 14 under 35 U.S.C. § 103(a) as being unpatentable over *Conn et al.* in view of *Glikfeld et al.* (U.S. Patent No. 5,279,543) is respectfully traversed. At a minimum, *Conn et al.* and *Glikfeld et al.* do not teach or suggest with sufficient specificity the range of contact area recited in independent claim 1.

As presently written, independent claim 1, from which rejected claim 14 depends, recites a range of contact areas between 0.01 and 50 mm^2. *Conn et al.* does not disclose the contact areas recited in independent claim 1 with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Glikfeld et al. describes devices for non-invasive sampling or delivery of substances in which electrodes range in size from 1μm^2 to 400 cm^2 (col. 11, lines 20-22)—a broad range that corresponds to an electrode area of 1 x 10^{-6} mm^2 to 40,000 mm^2. Applicants respectfully submit that the description in *Glikfeld et al.* does not disclose the claimed contact areas with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Thus, inasmuch as neither of *Conn et al.* nor *Glikfed et al.* teaches or suggests the contact areas recited in independent claim 1 with sufficient specificity, and in view of the surprising and unexpected results achieved by the claimed contact areas, Applicants respectfully submit that independent claim 1 and claim 14 dependent thereon are neither anticipated by nor would have been obvious in view of these references, individually or in combination. Accordingly, withdrawal of this ground of rejection is respectfully requested.

3. The rejection of claims 12 and 16 under 35 U.S.C. § 103(a) as being unpatentable over *Conn et al.* in view of *Ackerman* (U.S. Patent Publication No. 2003/0208114) is respectfully traversed. At a minimum, *Conn et al.* and *Ackerman* do not teach or suggest with sufficient specificity the range of contact area recited in independent claim 1.

As presently written, independent claim 1, from which rejected claims 12 and 16 depend, recites a range of contact areas between 0.01 and 50 mm^2. *Conn et al.* does not disclose the contact areas recited in independent claim 1 with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Ackerman describes methods of monitoring glucose levels using electrodes "configured to provide a geometric surface area of about 0.1 to 3 cm^{2}" (page 7, paragraph 67)—a broad range that corresponds to an electrode area of 10 mm^2 to 300 mm^2. Moreover, *Ackerman* identifies a most preferred area of 1 cm^2 (100 mm^2), which lies well above the upper limit recited in the claimed invention. Applicants respectfully submit that the description in *Ackerman* does not disclose the claimed contact areas with sufficient specificity for at least the reasons set forth above in the remarks addressing the rejection under 35 U.S.C. § 102(b).

Thus, inasmuch as neither of *Conn et al.* nor *Ackerman* teaches or suggests the contact areas recited in independent claim 1 with sufficient specificity, and in view of the surprising and unexpected results achieved by the claimed contact areas, Applicants respectfully submit that independent claim 1 and claims 12 and 16 dependent thereon are neither anticipated by nor would have been obvious in view of these references, individually or in combination. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Allowable Subject Matter

The allowance of independent claim 38 is noted with appreciation.

The Examiner's indication that claims 21 and 23 contain allowable subject matter is noted with appreciation. Since independent claim 19 is neither anticipated by nor would have been obvious in view of any of the cited references, individually or in combination, for at least the reasons set forth above, Applicants respectfully submit that claims 21 and 23, which depend from claim 19, are allowable as presently written.

The Examiner's further indication that claims 30-31, 33, and 37 contain allowable subject matter is likewise noted with appreciation. Since independent claim 29 is neither anticipated by nor would have been obvious in view of any of the cited references, individually or in combination, for at least the reasons set forth above, Applicant respectfully submits that claims 30-31, 33, and 37 which depend from claim 29, are allowable as presently written.

Conclusion

In view of the Amendment and Remarks set forth above, Applicants respectfully submit that the claimed invention is in condition for allowance. Early notification to such effect is earnestly solicited.

If for any reason the Examiner feels that the above Amendment and Remarks do not put the claims in condition to be allowed, and that a further discussion would be helpful to advance prosecution, it is respectfully requested that the Examiner contact the undersigned agent directly at (312)-321-4257.

Respectfully submitted,

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